

REMARKS**Status of the Claims**

Claims 22 and 24 are pending in the application. Claims 22 and 24 are rejected. Claim 22 is amended herein.

Claim amendments

Claim 22 is amended to overcome 35 U.S.C. §112, second paragraph rejection. Amended claim 22 now recites a kit for detecting Tumor Antigen Derived Gene-15 (TADG-15) protein. This kit comprises an antibody, wherein the antibody is specific for TADG-15 protein and detectable labels to label the antibody.

Amendments to Specification

The Examiner objected to the disclosure because it contained an embedded hyperlink and/or other form of browser-executable code on page 55, line 16.

In response, Applicants have amended the paragraph beginning on page 55, line 13 to delete the above-mentioned defect and to correct the grammar.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 22 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner states that claim 22 is vague and indefinite since it recites detectable labels for detecting said antibody and does not specify if (1) the antibody is labeled; (2) a secondary antibody that detects the first antibody is labeled; (3) there is free label in the kit; and (4) the protein is labeled.

Claim 22 has been amended as discussed above. Based on this amendment it is very clear that the kit comprises labels to label the antibody in order for the kit to effectively detect TADG-15 protein. The Applicants' specification teaches various labels that can be used for this purpose (page 42, line 1 to page 43, line 20). However, Applicants respectfully submit that a person having

ordinary skill in this art would be able to readily recognize suitable labels other than one discussed which might be used to label the antibody. Further, the binding of these labels to the antibodies can be accomplished using standard techniques known and used by those of ordinary skill in the art. Accordingly based on the amendment and remarks, Applicants respectfully request the withdrawal of rejection of claim 22 under 35 U.S.C. §112, second paragraph.

The 35 U.S.C. §102 Rejection

Claim 24 stands rejected under 35 U.S.C. §102(b) as being anticipated by Japanese document, J09149790-A (10 June 1997). Applicants respectfully traverse this rejection.

In the Final Office Action mailed July 27, 2004, the Examiner notes that Applicants' claims do not include limitations that preclude the prior art's antibody from binding the TADG-15 protein. Applicants respectfully disagree with the Examiner. Specificity of antibody or antiserum is defined by its ability to discriminate between the antigen against which it was made and any other antigen one might test (Paul Fundamental Immunology,

Fourth Edition, pg 91, lines 11-14). Therefore since the kit of the instant invention is designed to specifically detect TADG-15 protein, antibody that binds only to TADG-15 protein and not to other related proteins will be included in the kit. The antibody directed against the isolated protein in the Japanese document would bind to the serine protease domain of the TADG-15 protein in addition to binding to the TADG-15 protein. Therefore, one skilled in the art would not anticipate the use of this antibody in a kit specifically designed to detect TADG-15 protein. Thus, by reciting "specific for TADG-15 protein", the claim precludes prior art's antibody from being included in the kit. In addition, the Examiner has not produced any scientific evidence establishing that the antibody directed against the isolated protein in the cited Japanese document J09149790-A would bind specifically to Applicants' TADG-15 protein. Accordingly based on these remarks, Applicants respectfully request withdrawal of rejection of claim 24 under 35 U.S.C. §102(b).

The 35 U.S.C. §103 Rejection

Claims 22 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Japanese document, J09149790-A (10 June 1997), in view of Harlow and Lane (Antibodies, A Laboratory Manual, pages 319, 321-325 and 340-352, 1988). Applicants respectfully traverse this rejection.

In the Final Office Action mailed July 27, 2004, the Examiner states that a person having ordinary skill in this art would have been motivated to implement the teachings of the cited references, i.e., J09149790-A (which teaches of an antibody specific to Applicants' TADG-15 protein) and Harlow and Lane (which teaches labeling of antibodies to be used in a wide range of immunological techniques) in order to create labeled antibodies and antibody-conjugates in order to use them in a number of applications.

Applicants respectfully disagree with the Examiner. J09149790-A teaches the sequence of an isolated protein. Furthermore, J09149790-A contemplates generating antibodies to that isolated protein. Although this sequence matches with the serine protease domain of the TADG-15 protein of the instant

invention, J09149790-A does not teach of the rest of the sequence of TADG-15 protein as is taught by the instant invention. In fact, the instant invention teaches the complete cloning and sequencing of the TADG-15 protein, a unique form of serine protease that was not previously described in the literature. Therefore, if a person having ordinary skill in this art were to implement the teachings of J09149790-A to generate antibody as recited in the claim of the instant invention, one would never be able to generate an antibody that binds only to TADG-15 protein. Thus, any motivation found for one of ordinary skill in the art at the time of the instant invention to generate an antibody specific to TADG-15 protein is provided by the instant invention.

Even assuming *arguendo*, should one of ordinary skill in the art be motivated by J09149790-A, one would merely be trying absent the teachings or suggestions of the instant invention to generate an antibody that is specific for TADG-15 protein. It has long been established that "obvious to try" is not the legal standard for obviousness. Therefore since J09149790-A does not teach of the antibody specific for TADG-15 protein, the combined teachings of the two cited prior arts do not teach all elements of the

composition of the kit either. Accordingly based on these remarks, Applicants respectfully request the withdrawal of rejection of claims 22 and 24 under 35 U.S.C. 103(a).

This is intended to be a complete response to the Office Action mailed July 27, 2004. Applicants submit that the pending claims are in condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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